K111316

JUL 20 2011

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the *aap* Cannulated Screws 2.7-7.5.

Submitted By:	*aap* Implantate AG Lorenzweg 5 12099 Berlin Germany Phone: +49 30 750 19 0 Fax: +49 30 750 19 111
Date:	May 6, 2011
Contact Person:	Marc Seegers, Dipl.-Ing. Director QA/ RA Lorenzweg 5 12099 Berlin Germany Phone: +49 30 750 19 192 Fax: +49 30 750 19 111
Proprietary Name:	*aap* Cannulated Screw
Common Name:	Cannulated Screw
Classification Name and Reference:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener - Class II
Device Product Code and Panel Code:	Orthopedics/87/ HWC

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DEVICE INFORMATION

A INTENDED USE

The *aap* Cannulated Screw is intended for use over a guide pin or wire for bone fracture fixation and bone fragment fixation. *aap*'s washers may be used with the screws in certain applications.

- minimally invasive reconstruction of fractures and joints
- adjuvant for osteosynthesis in complex joint fractures
- multifragment joint fractures
- fractures of the femoral head and neck
- supracondylar femoral fractures
- tibial plateau fractures
- simple metaphyseal fractures
- simple epiphyseal fractures such as:
    - fractures of the humeral head
    - fractures of the tibial plateau
    - pilon fractures
    - fractures of the radius
- fractures of the wrist, ankle, elbow, and shoulder
- scaphoid fracture and other fractures of the hand
- metatarsal fractures and other fractures of the foot
- ligament fixation at the proximal humerus
- acetabular fractures
- fractures of the posterior pelvic ring
- condylar fractures
- epiphyseal and metaphyseal fractures in children
- ligament avulsion injuries
- fractures of small joints, such as:
    - ankle fractures
    - navicular fractures
- calcaneal and talar fractures
- arthrodesis of the ankle
- avulsion fractures and fractures of metatarsal V
- tarsal fractures

B DEVICE DESCRIPTION

The *aap* Cannulated Screws are manufactured from Titanium Alloy conforming to ASTM F136 or ISO 5832-3 and Stainless Steel conforming to ASTM F138 or ISO 5832-1. The Screws are offered in varying overall lengths and thread lengths to accommodate variability among patients.

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C DESCRIPTION OF DEVICE MODIFICATION

This special 510(k) submission is intended to introduce a line extension to the predicate aap Small and Large Cannulated Screw System (K021233) and aap Cannulated Screws (K080101), which consists of the addition of new overall lengths and thread lengths both for titanium alloy and stainless steel screws.

D SUBSTANTIAL EQUIVALENCE INFORMATION

The design features, material, and indications for use of the *aap* Cannulated Screws 2.7-7.5 are substantially equivalent to the previously cleared *aap* Small and Large Cannulated Screw System (K021233) and *aap* Cannulated Screws (K080101). The safety and effectiveness of the *aap* Cannulated Screws is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

E SUMMARY OF VERIFICATION ACTIVITIES

Documentation is provided which demonstrates that the additional screws to be substantially equivalent to the predicate devices in terms of material, design, mechanical performance and indications for use. Mechanical tests per ASTM F543 were conducted for those screws for which no test reports have been provided with the predicate device submissions K021233 and K080101 to verify the safety and effectiveness of the additional screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

aap Implantate AG
% Marc Seegers, Dipl.-Ing.
Director, Quality Assurance/Regulatory Affairs
Lorenzweg 5
Berlin, Germany 12099

JUL 20 2011

Re: K111316
Trade/Device Name: aap Cannulated Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 30, 2011
Received: July 05, 2011

Dear Mr. Seeger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111316

Device Name: *aap* Cannulated Screws 2.7-7.5

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Mellerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111316